

# PATENT COOPERATION TREATY

# PCT

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## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 32349P WO		<b>FOR FURTHER ACTION</b>		See Form PCT/IPEA/416
International application No. PCT/EP2004/014684		International filing date (day/month/year) 23.12.2004	Priority date (day/month/year) 23.12.2003	
International Patent Classification (IPC) or national classification and IPC INV. B01J13/00				
Applicant MEDIGENE ONCOLOGY GMBH				
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>				
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input checked="" type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>				
Date of submission of the demand  13.07.2005		Date of completion of this report  13.04.2006		
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016		Authorized officer  Willsher, C  Telephone No. +31 70 340-2649		



**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/EP2004/014684

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**Box No. I Basis of the report**

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1. With regard to the **language**, this report is based on

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of:
  - ☐ international search (under Rules 12.3(a) and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4(a))
  - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements**\* of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

**Description, Pages**

1-44 as originally filed

**Claims, Numbers**

1-17 as originally filed

**Drawings, Sheets**

1/4-4/4 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

\* *If item 4 applies, some or all of these sheets may be marked "superseded."*

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**Box No. IV Lack of unity of invention**

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1. ☐ In response to the invitation to restrict or pay additional fees, the applicant has, within the applicable time limit:
- ☐ restricted the claims.
  - ☐ paid additional fees.
  - ☐ paid additional fees under protest and, where applicable, the protest fee.
  - ☐ paid additional fees under protest but the applicable protest fee was not paid.
  - ☐ neither restricted the claims nor paid additional fees.
2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is:
- ☐ complied with.
  - ☒ not complied with for the following reasons:  
**see separate sheet**
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☒ all parts.
  - ☐ the parts relating to claims Nos. .

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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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1. Statement

Novelty (N)	Yes: Claims	16
	No: Claims	1-15,17
Inventive step (IS)	Yes: Claims	
	No: Claims	16
Industrial applicability (IA)	Yes: Claims	1-17
	No: Claims	

2. Citations and explanations (Rule 70.7):

**see separate sheet**

**INTERNATIONAL PRELIMINARY REPORT  
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International application No.  
PCT/EP2004/014684

1. US-A-5 556 580 (Document D1) discloses a method in which liposomes are extruded through a frit (1) by means of a piston pump (16) and arrive in collection vessel (22) - see Fig. 2; column 5, lines 27-44; Examples 1-4. The liposome material contains water (column 7, lines 31 and 56), which means that an aqueous medium will exist in collection vessel 22 to disperse the extruded composition emerging from frit (1). Pressures exceeding 1000 psi (=68 bar) are "most preferred" (column 6, lines 3-4), which must result in homogeneity on a molecular level of the extruded material. Indeed, this pressure falls within the range recited in present claim 10. The subject-matter of present claims 1-15 and 17 is thereby known. In this respect, it is pointed out that the parameters of the product (cf. present claims 3 and 6) are regarded as implicitly disclosed in D1 and cannot establish novelty, and that the step of supply the intermediate product to a hydration process (claim 14) is not part of the nanoparticle production process, and is therefore ignored for the purpose of examination for novelty.
2. By similar reasoning, the subject-matter of present claims 1-15 and 17 is considered to be anticipated by Examples 1-18 (in particular Example 11) and claims 1-10 of EP-A-0 460 720 (Document D2).
3. Claims 1-15, 17 do not fulfill the requirement of Article 33(2) PCT.
4. The dimensions of the compounder given in present claim 17 are not recited in D1 or D2. However, no inventive step can be recognised, since these dimensions do not appear to give rise to any surprising effect, and thus do not contribute to solving the technical problem.
5. Present claim 17 does not fulfill the requirement of Article 33(3) PCT.
6. Further to paragraph 4, above, it is noted that independent claim 1 does not give the dimensions of the compounder, as recited in independent claim 16. This is taken as further evidence that the said dimensions play no part in solving the technical problem, since their absence in claim 1 implies they are unimportant. Furthermore, the subject-matter common to claims 1 and 16 is simply a compounder, which is known from both D1 and D2. Claim 16 therefore forms an invention having no unitary link with claims 1-15 and 17. The unity requirement of Rule 13.1 PCT is not met.